

REMARKS

I. Amendment to the Specification

The specification has been amended to add the priority information necessary to comply with 35 U.S.C. § 119(e) and 37 C.F.R. § 1.78. Applicants previously made a proper claim to priority under Article 8 of the Patent Cooperation Treaty (See Box No. VI of the PCT Request filed January 28, 2000).

II. Pending Claims

By the current amendment, claims 4, 7, 11, 13-14, and 17-23 have been canceled, and claims 24-27 are newly added. Accordingly, claims 1-3, 5-6, 8-10, 12, 15-16, and 24-27 are pending in the instant Application. Applicants have also amended claims 1, 2, and 10. Support for the amendments may be found in the language of the claims as originally filed. Addition of the new claims serves to further clarify the subject matter which Applicants consider to be the invention. Newly added claim 24 is drawn to a microarray; newly added claims 25-27 are drawn to methods of using the claimed polynucleotides.

III. Comments Regarding Restriction Requirement

Applicants hereby elect, with traverse, to prosecute Group 16 which corresponds to claims 1-2, 8, and 15-16, and is drawn to the special technical feature of an isolated polypeptide, the first claimed method of making, and a pharmaceutical composition comprising a polypeptide, and the first claimed method of use, i.e., a method of using a pharmaceutical composition comprising a polypeptide for treating a disease.

Further, Applicants elect, with traverse, to prosecute claims related to the polypeptide sequence of SEQ ID NO:19, which is encoded by SEQ ID NO:74, and which sequences read on claims 3-6 and 10-11.

Applicants reserve the right to prosecute the subject matter of non-elected claims in subsequent divisional applications. Applicants traverse both the restriction requirement and the obligation to elect a

single sequence for prosecution which were imposed in the Restriction Requirement mailed February 10, 2004 for at least the following reasons.

A. The unity of invention standard *must* be applied in national stage applications

Section 1850 of the Manual of Patent Examining Procedure (original 8th edition, published August, 2001) (hereinafter "MPEP") provides:

... [W]hen the Office considers international applications ... during the national stage as a Designated or Elected Office under 35 U.S.C. 371, PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111....

In applying PCT Rule 13.2 to ... national stage applications under 35 U.S.C. 371, examiners should consider for unity of invention all the claims to different categories of invention in the application and permit retention in the same application for searching and/or preliminary examination, claims to the categories which meet the requirements of PCT Rule 13.2....

Id at page 1800-60 to -61.

MPEP section 1893.03(d) reiterates the Examiner's obligation to apply the Unity of Invention standard PCT Rule 13.2 instead of U.S. restriction/election of species practice:

Examiners are reminded that unity of invention (not restriction) practice is applicable ... in national stage (filed under 35 U.S.C. 371) applications.

Id at page 1800-149, column 1.

B. Specific provisions of the Administrative Regulations Under the PCT and the corresponding provisions of the MPEP strongly support a finding of unity of invention among all of the claims in the present case

1. Unity of Invention is accepted between claims to polypeptides and claims to the polynucleotides which encode them

Example 17, Part 2 of Annex B to the Administrative Instructions Under the PCT provides that unity of invention is accepted between a protein and the polynucleotide that encodes it:

Example 17

Claim 1: Protein X.

Claim 2: DNA sequence encoding protein X.

Expression of the DNA sequence in a host results in the production of a protein which is determined by the DNA sequence. The protein and the DNA sequence exhibit corresponding special technical features. Unity between claims 1 and 2 is accepted.

Applicants submit that claims drawn to the elected polypeptide sequence of SEQ ID NO:19 (*i.e.*, claims 1, 2, 8, and 15-16 of Group 16) and claims drawn to the polynucleotide sequence of SEQ ID NO:74, which encodes SEQ ID NO:19 (*i.e.*, claims 3-6 and 10-11), meet the unity of invention requirements.

Therefore, Applicants respectfully request that the Examiner withdraw the Restriction Requirement at least as to claims 1-3, 5-6, 9, 11, and 15-16, and examine those claims in a single application.

2. Unity of invention exists with respect to dependent claims in the same claim category as the independent claim from which they depend

MPEP section 1850(A) and 1893.03(d), which recite the provisions of paragraph (c) of Part 1 (entitled "Instructions Concerning Unity of Invention") of Annex B (entitled "Unity of Invention") to the Administrative Instructions Under the PCT, provides:

(A) Independent and Dependent Claims.

Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression "category of claim" referring to the classification of claims according to the subject matter of the invention claimed for example, product, process, use or apparatus or means, etc.).

(i) If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, **it does not matter if a dependent claim itself contains a further invention....** (*Emphasis added*).

See MPEP section 1850(A) at page 1800-61. See also MPEP Appendix AI at page 53.

Accordingly, claim 9, drawn to antibodies, should also be examined together with claim 1, drawn to the polypeptides from which claim 9 depends. Also, in the present case, claims 2, 3, 5-6, 9, and 15, all of which depend from claim 1, are all directed to compositions of matter, *i.e.*, to products. Further, as discussed above, there is unity of invention among claims 1 and 3.

Thus, it is improper to restrict claims 1-2 and 15 from claims 3-6 and 10-11, as the Examiner has done. Therefore, Applicants respectfully request that the Examiner withdraw the Restriction Requirement at least as to the composition of matter claims, and that at least those claims be considered together in a single application.

3. Unity of invention exists among all of Applicants' claims

MPEP 1850 provides:

Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art. The determination is made based on the contents of the claims as interpreted in light of the description and drawings. Annex B also contains examples concerning unity of invention.

Id at page 800-61.

MPEP 1893.03(d) similarly provides:

A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art. For example, a corresponding technical feature is exemplified by a key defined by certain claimed structural characteristics which correspond to the claimed features of a lock to be used with the claimed key. Note also examples 1-17 of Annex B Part 2 of the PCT Administrative Instructions as amended July 1, 1992 contained in Appendix AI of the MPEP.

Id at page 1800-149.

In the present case, unity of invention exists among all of Applicants' claims. The sequences of the claimed polypeptides and the sequences of the claimed polynucleotides encoding those polypeptides are corresponding technical features which are common to all of Applicants' claims, which serve to technically interrelate all of Applicants' claims, and which define the contribution over the prior art made by each of them. Thus, Applicants' claims are linked to form a single general inventive concept, and Applicants are therefore entitled to prosecute all of their pending claims in a single national stage application.

4. The claimed polypeptide sequences, and the claimed polynucleotide sequences encoding those polypeptide sequences, are corresponding technical features that are common to all of Applicants' claims and that serve to technically interrelate them

The sequences of the claimed polypeptides and corresponding polynucleotides are common to all of Applicants' claims, given that each claim refers to one or both either explicitly or implicitly, by virtue of depending from a claim which makes an explicit reference to the sequences of the claimed polypeptides or claimed polynucleotides.

Moreover, the sequences of the claimed polypeptides and corresponding polynucleotides serve to technically interrelate all of Applicants' claims. Applicants' composition of matter claims (1-3, 5-6, 9 10, 15, 24 and 26) are drawn to either the polypeptides or polynucleotides themselves (1 and 2, drawn to polypeptides, and 3, 5 10, and 26, drawn to polynucleotides), to compositions of matter which comprise the polypeptides or polynucleotides as one element (5 and 6, drawn to recombinant polynucleotides and transformed cells, respectively, and 15 and 16, drawn to pharmaceutical compositions), or to compositions of matter wherein the sequences of the claimed polypeptides functionally limit the claimed subject matter (claim 9, drawn to an antibody which specifically binds a polypeptide of claim 1).

In Applicants' method claims 8, 12, 16, 25, and 27, the claimed polypeptides or polynucleotides serve as either the product of the claimed method (claim 8, drawn to a method of polypeptide production) and/or as a reagent for performing the method (claim 12 drawn to methods of detecting a target polynucleotide in a sample; claim 16, drawn to a method of treating a disease or

condition associated with decreased expression of functional NuABP; claim 25, drawn to a method of generating an expression profile of a sample which contains polynucleotides; and claim 27, drawn to a method of screening a compound for effectiveness in altering expression of a polynucleotide of claim 3).

Therefore, the claimed polypeptide and polynucleotide sequences are corresponding technical features which are common to all of Applicants' claims, and which serve to technically interrelate them. Applicants' claims are linked to form a single general inventive concept, and Applicants are therefore entitled to prosecute all of their pending claims in a single national stage application. Withdrawal of the restriction requirement in the present case is therefore respectfully requested.

5. Minimal burden to search claims 9, 10 and 15 under U.S. practice

Applicants also respectfully submit that the search required to identify prior art relevant to the polynucleotides of SEQ ID NO:74 should substantially overlap with that required for examination of the elected polypeptides of Group 16. In addition, there is minimal additional burden on the Examiner to examine claim 12, and newly added claims 25-27, which are drawn to methods of using the claimed polypeptides, and newly added claim 24, which is drawn to a microarray using the claimed polynucleotides.

III. Rejoinder of method claims upon allowance of product claims under U.S. practice

The Examiner is reminded that claim 8 is drawn to a method of producing the elected polypeptides of Group 16, and should be rejoined per the Commissioner's Notice in the Official Gazette of March 26, 1996, entitled "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," which sets forth the rules that upon allowance of any of the product claims, the method claims covering the same scope of products be rejoined. Applicants request that claim 8 be rejoined and examined upon allowance of any claim drawn to the elected polypeptides.

It is noted that, while Applicants have canceled and not repeated new versions of the claims drawn to a transgenic organisms or claims drawn to agonists and antagonists. Applicants expressly assert that these claims have been canceled for reasons relating to cost and efficiency of prosecution of

the presently elected claims, and not for reasons relating to patentability. Applicants further expressly reserve the right to pursue the subject matter of those canceled claims, or any other subject matter disclosed but not herein claimed, in a later continuation or divisional application.

The Election of Species Requirement

Applicants elect, with traverse, to prosecute claims related to the polypeptide sequence of SEQ ID NO:19, which is encoded by the polynucleotide sequence of SEQ ID NO:74.

CONCLUSION

In light of the above amendments and remarks, Applicants submit that the present application is fully in condition for allowance, and request that the Examiner withdraw the outstanding objections/rejections. Early notice to that effect is earnestly solicited.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact the undersigned at the number listed below.

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. **09-0108**.

Respectfully submitted,

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